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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,544	03/19/2002	Laurent Di Costanzo	C1190/20009	7903

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CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.
12TH FLOOR, SEVEN PENN CENTER
1635 MARKET STREET
PHILADELPHIA, PA 19103-2212

EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/26/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,544

Applicant(s)

COSTANZO ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, both received on 30 June 2003.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 2, 3, 6, 7, 11, and 12 under 35 U.S.C. 112, second paragraph, as being indefinite is hereby withdrawn.

Claim 1 remains rejected for containing the reference to criteria found in the French Pharmacopoeia. All claims must be complete in and of themselves.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 has been amended so that the particle size properties of the lubricating agent are vague and insufficiently defined. It is the position of the examiner that by removing the limitation of any specific particle size distribution from Claim 7, the applicant has rendered the claim indefinite.

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Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 3-6, 8-11 under 35 U.S.C. 102(e) as being anticipated by Liu *et al.* is hereby withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-12 under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.* is hereby withdrawn.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.* in view of Schmitz *et al.* (U.S. Patent No. 6,079,168)

The Liu *et al.* patent teaches pharmaceutical dosage forms for a rapidly disintegrating buccal tablet (See Column 1, Line 49 to Column 2, Line 3). The tablets dissolve in about 1 to about 40 seconds in an aqueous solution, which is typically saliva (See Column 2, Lines 45-51). Processes for making this tablet are disclosed (See Column 2, Line 52 to Column 3, Line 55). The tablets can comprise saccharides of various moldabilities, including mannitol, lactose, glucose, sucrose, lactitol, maltose, maltitol, and sorbitol (See Column 2, Lines 27-39). A lubricant, such as magnesium stearate, can be included in the tablets in amounts ranging from 0.1% to 2.0% by weight of the tablet (See Column 7, Lines 55-63). A disintegrant may be

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included as well, such as croscarmellose sodium and sodium starch glycolate (See Column 7, Line 64 to Column 8, Line 2). Other additives may also be included as well, such as colorants and sweeteners (See Column 8, Lines 29-45). The use of polyvinylpyrrolidone as a binder for the purpose of reducing the friability of a tablet is disclosed, and examples are given that illustrate how friability can be manipulated to below 1.0% (See Column 7, Lines 21-34; and Examples). In particular, Example 7 shows one set of tablets that exhibit a friability of about $2.7 \pm 2.2\%$, which the examiner will interpret to mean a range from about 0.5% to about 4.9%. In Example 8, Tablet B exhibits a friability of $0.8 \pm 0.5\%$. The limitations in Claim 1 regarding its ability to be packaged is interpreted to be directed toward a future intended use of the tablet, and is therefore not given any patentable weight. Claim 10 is directed toward a future intended use of the claimed tablet, and this limitation of intended use is not given patentable weight by the examiner. Therefore, the examiner considers the tablet of Claim 10 to be anticipated by the prior art.

The Liu *et al.* patent does not explicitly teach methods of manufacturing tablets wherein the lubricant is entirely or mostly applied to the outer surface of the tablet.

The Schmitz *et al.* patent discloses a device that sprays powdered lubricants onto punches and dies of a tablet press. Such a device can be readily retrofitted into existing machinery and provide an improved method of tablet manufacture (See Column 1, Line 35 to Column 3, Line 36).

It would be obvious to one of ordinary skill in the art to combine the disclosures of Liu *et al.* and Schmitz *et al.* into the objects of the present invention. One of ordinary skill in the art would be motivated to do so in order to produce tablets using an optimized manufacturing

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process. By the disclosure of the Schmitz *et al.* patent regarding the ease with which existing tablet presses can be modified to include the disclosed lubricant spraying device, one of ordinary skill would have a reasonable expectation of success in making this modification. Since the dies and punches of the tablet press are sprayed with a powdered lubricant, it would be obvious to one of ordinary skill in the art that in the resulting manufactured tablets, the lubricant would be present mostly or entirely on the surface of the tablets.

The limitations of Claims 2, 7, 12, 14, and 17-20 are not considered to be critical to the function of the instantly claimed invention. Absent a showing of criticality or of results that would be unexpected by one of ordinary skill in the art at the time the invention was made, these claims are not considered to be patentable above the prior art. The examiner also points out in Liu *et al.*, Column 4, Lines 35-48, there is a description of the moldability of various saccharides, which the examiner will interpret to read on various process conditions, particularly die diameters and compression pressures. Regarding Claims 7, 17, and 18 in particular, the Schmitz *et al.* patent discloses the adherence of the powdered lubricant to the tablet press punch surfaces (See Column 2, Lines 10-24). It is the position of the examiner that in addition to adjusting operational parameters of the device disclosed in Schmitz *et al.*, it would also be obvious to one of ordinary skill in the art to influence lubricant adhesion to the punch surfaces by other factors, such as the selection of a particular lubricant, or its specific physical properties, such as particle size.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.* in view of Schmitz *et al.* and Valentine (U.S. Patent No. 6,684,534).

The relevant portions of Liu *et al.* and Schmitz *et al.* are detailed in the above rejection of Claims 1-16, 19, and 20 under 35 U.S.C. 103(a).

The Liu *et al.* and Schmitz *et al.* patents do not explicitly disclose particle sizes of lubricants to be used in manufacturing tablets.

The Valentine patent is relied upon here as a teaching reference, stating that lubricants, having a particle size of 44 microns or less are known and desired within the art of manufacturing tablets. Furthermore, these lubricants may be further screened for smaller particle sizes (See Column 5, Line 54 to Column 6, Line 3).

It would be obvious to one of ordinary skill in the art to combine the disclosures of Liu *et al.*, Schmitz *et al.*, and Valentine into the objects of the present invention. One of ordinary skill in the art would be motivated to do so in order to produce tablets using an optimized manufacturing process. By the disclosure of the Schmitz *et al.* patent regarding the ease with which existing tablet presses can be modified to include the disclosed lubricant spraying device, one of ordinary skill would have a reasonable expectation of success in making this modification. Since the dies and punches of the tablet press are sprayed with a powdered lubricant, it would be obvious to one of ordinary skill in the art that in the resulting manufactured tablets, the lubricant would be present mostly or entirely on the surface of the tablets. The Valentine patent, being relied upon merely as a teaching reference, is used to demonstrate that lubricants with particle sizes in the ranges claimed by the applicant in Claims 17 and 18 are known in the art.

The limitations of Claims 2, 7, 12, 14, and 17-20 are not considered to be critical to the function of the instantly claimed invention. Absent a showing of criticality or of results that

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would be unexpected by one of ordinary skill in the art at the time the invention was made, these claims are not considered to be patentable above the prior art. The examiner also points out in Liu *et al.*, Column 4, Lines 35-48, there is a description of the moldability of various saccharides, which the examiner will interpret to read on various process conditions, particularly die diameters and compression pressures. Regarding Claims 7, 17, and 18 in particular, the Schmitz *et al.* patent discloses the adherence of the powdered lubricant to the tablet press punch surfaces (See Column 2, Lines 10-24). It is the position of the examiner that in addition to adjusting operational parameters of the device disclosed in Schmitz *et al.*, it would also be obvious to one of ordinary skill in the art to influence lubricant adhesion to the punch surfaces by other factors, such as the selection of a particular lubricant, or its specific physical properties, such as particle size.

Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 30 June 2003 have been fully considered but they are not persuasive.

As the applicant contends the inventive concept of the presence of the majority or the entirety of a lubricating agent on the surface of the instantly claimed tablet, the examiner has relied upon the Schmitz *et al.* patent in order obviate this particular feature. The examiner has also relied upon Valentine as a teaching reference in order to make stronger rejection of the claims, particularly with respect to Claims 17 and 18.

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The applicant still has not addressed the rejection of Claim 1 for referring to the French Pharmacopoeia. Furthermore, the applicant's amendment of Claim 7 has introduced a new issue of indefiniteness to that claim. All previously pending claims remain rejected and all new claims are rejected.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sj0

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600